UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/820,339	03/29/2001	Sara Fuchs	FUCHS=2A	3100

1444 7590 11/15/2006

BROWDY AND NEIMARK, P.L.L.C.
624 NINTH STREET, NW
SUITE 300
WASHINGTON, DC 20001-5303

EXAMINER	
HAYES, ROBERT CLINTON	

ART UNIT	PAPER NUMBER
1649	

DATE MAILED: 11/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/820,339	FUCHS ET AL.	
	Examiner	Art Unit	
	Robert C. Hayes, Ph.D.	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8,9,12,14-18,25,27,30,31 and 36-41* is/are pending in the application.

4a) Of the above claim(s) ___ is/are withdrawn from consideration.

5)☒ Claim(s) *12* is/are allowed.

6)☒ Claim(s) *8,9,15-18,30,31 and 36-39* is/are rejected.

7)☒ Claim(s) *14,25,27,40 and 41* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. The amendment filed 8/21/06 has been entered.

2. Applicants' arguments filed 8/21/06 have been considered but are not found persuasive.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. It is again noted that the rejection of claims 8, 9, 16-18, 30 & 36-39 under 35 U.S.C. 102(b) as being anticipated by Schoepfer et al. (1988), was withdrawn solely because of the "proviso" now recited in claim 8. Note again that this rejection will likely be re-instated should Applicants obviate the new matter rejection below.

5. Claim 12 is allowed.

6. Claims 14, 25, 27 & 40-41 stand objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

7. Claims 8, 9, 15-18, 30-31 & 36-39 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons made of record in Paper No. 20060419, and as follows.

In contrast to Applicants' arguments on page 9 of the response, the mere "positive" recitation of Hα1-210 is not reasonably equivalent to an "exclusionary proviso [with] basis in the original disclosure", which alternatively must be explicitly stated within the original specification. Nor is the recitation of "in which one or more amino acid residues have been added..." reasonably equivalent to the negative proviso of not consisting of "or said sequence and one additional residue".

Similar to that previously made of record, no proper antecedent basis not conception in context with that described within the specification at the time of filing the instant application still exists for the negative recitation of "with the proviso that said polypeptide tolerogen does not consist of a sequence consisting of residues 1-210 of SEQ ID NO: 2, or said sequence and one additional residue" after the functional language previously suggested by the Examiner related to α-bungarotoxin. No such basis exists on pages 9-10 nor 20 of the specification in contrast to Applicants' assertions; thereby, still constituting new matter.

It is alternatively noted that the courts have held that negative limitations that exclude compounds do not meet the requirements of 35 U.S.C. 112 because it attempts to claim the invention by excluding what was not invented rather than what was invented. *In re Schechter, 205 F2d 185, 98 USPQ 144 (CCPA 1953).* Thus, Applicants' arguments are not persuasive.

8. Claims 36-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons made of record in Paper No. 20060419, and as follows.

It remains ambiguous how a "polypeptide tolerogen [that] does not consist of residues 1-210 of SEQ ID NO: 2" can also "consist... of amino acid residues 1-210 of SEQ ID NO: 2" as recited in (c), which remains contradictory. In contrast to Applicants' arguments on page 10 of the response, addition of an alternative proviso (i.e., "or") does not obviate this rejection, because the other negative limitation to these claims still remains.

9. Claims 8, 16-18, 30 & 36-39 stand rejected under 35 U.S.C. 102(b) as being anticipated by Talib et al. (1991; IDS Ref #AM), for the reasons made of record in Paper NOs: 11 (mailed 1/30/03), 14 (mailed 10/14/04), 20040721, 20050603 & 20060419, and as follows.

In contrast to Applicants' arguments on pages 10-11 of the response, the additional alternative recitation of "**or** said sequence and one additional residue" does not obviate the previous claim limitations, because this recitation only broadens the claims, and limits nothing already recited. Therefore, these claims remain anticipated by the teachings of Talib, for the reasons previously made of record.

Note that amending claim 8 to delete (iv) may obviate the rejection of some of these claims.

As previously made of record, the sole difference between Talib's sequence and DNA encoding Hα1-210 of claims 8(iv), 30 & 36 is the mere addition/fusion of the Met start codon

residue at the N-terminal end of SEQ ID NO: 2, as indicated in Figure 1, which therefore, meets the "proviso that said tolerogen does not consist of residues 1-210 of SEQ ID NO: 2". In that this Met start codon is inherently removed during proteolytic processing of eukaryotic proteins, Talib's DNA then "cod[es] for a polypeptide tolerogen ... consisting of amino acid residues [1-210] of SEQ ID NO: 2". This fusion polypeptide of Talib also inherently "does not assume the native conformation of the α subunit of the human acetylcholine receptor" because Talib's polypeptide constitutes a truncated version of the human acetylcholine receptor which is the extracellular domain of this receptor subunit. Note, pages 20 & 26 of the specification disclose that the AChR α-subunit *extracellular* domain polypeptide itself functions as a tolerogen. Note further that it is well known in the art that polypeptides produced in *E.coli*, as taught by Talib, often are not properly folded, and therefore, do "not assume the native conformation of the α-subunit of the human acetylcholine receptor", as recited. Nevertheless, *in arguendo,* because Talib teach a structure identical to that claimed, inherently it reasonably possesses any functional properties associated with that claimed structure. Thus, Applicants' arguments remain not persuasive, and are not on point with that actually claimed.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (571) 272-0885. The examiner can normally be reached on Monday through Thursday from 9:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on (571) 272-0867. The fax phone number for this Group is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert C. Hayes, Ph.D.
November 9, 2006

ROBERT C. HAYES, PH.D.
PRIMARY EXAMINER